Af/3736

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Application Number	09/662,927
Filing Date	September 15, 2000
First Named Inventor	Marvin J. Slepian
Art Unit	3736
Examiner Name	Matthew J. Kremer
Attorney Docket Number	MJS 101

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Firm or Individual	Patrea L. Pabst, Esq., Reg. No. 31,284 Holland & Knight LLP Suite 2000, One Atlantic Center; 1201 West Peachtree Street, N.E.; Atlanta, GA 30309-3400
Signature	
Date	March 21, 2003

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☑ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 160.00

Complete if Known	
Application Number	09/662,927
Filing Date	September 15, 2000
First Named Inventor	Marvin J. Slepian
Examiner Name	Matthew J. Kremer
Art Unit	3736
Attorney Docket No.	MJS 101

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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
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1002	330	2002	165	Design filing fee	
1003	520	2003	260	Plant filing fee	
1004	750	2004	375	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

			Extra Claims		Fee from below		Fee Paid
Total Claims	18	-38	0	X	0	=	0
Independent Claims	2	- 4** =	0	X	0	=	0
Multiple Dependent						=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	84	2201	42	Independent claims in excess of 3
1203	280	2203	140	Multiple dependent claim, if not paid
1204	84	2204	42	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

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1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	410	2252	205	Extension for reply within second month	
1253	930	2253	465	Extension for reply within third month	
1254	1,450	2254	725	Extension for reply within fourth month	
1255	1,970	2255	985	Extension for reply within fifth month	
1401	320	2401	160	Notice of Appeal	
1402	320	2402	160	Filing a brief in support of an appeal	160.00
1403	280	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,300	2453	650	Petition to revive - unintentional	
1501	1,300	2501	650	Utility issue fee (or reissue)	
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SUBMITTED BY				(Complete *if applicable*)	
Name (Print/Type)	Patrea L. Pabst	*Registration No. (Attorney/Agent)*	31,284	*Telephone* (404) 817-8473	
Signature				*Date*	March 21, 2003

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MJS 101 079610/00003

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Marvin J. Slepian

Serial No.: 09/662,927 Art Unit: 3736

Filed: September 15, 2000 Examiner: Matthew J. Kremer

For: *SENSING, INTERROGATING, STORING, TELEMETERING AND RESPONDING MEDICAL IMPLANTS*

Assistant Commissioner for Patents
Washington, D.C. 20231

APPEAL BRIEF

Sir:

This is an appeal from the final rejection of claims 1-9, 19, 22, 23, 27, 28 and 30-33 in the Office Action mailed September 20, 2002 in the above-identified patent application. A Notice of Appeal was mailed on January 21, 2003. A check in the amount of $160.00 for the filing of this Appeal Brief for a small entity is also enclosed. It is believed that no additional fee is required with this submission. However, should an additional fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-1868.

(1) REAL PARTY IN INTEREST

The real party in interest of this application is the assignee, Endoluminal Therapeutics, Inc., Tucson, Arizona.

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to appellant, the undersigned, or appellant's assignee which directly affects, which would be directly affected by, or which would have a bearing on the Board's decision in this appeal.

(3) STATUS OF CLAIMS ON APPEAL

Claims 1-9, 19, 22, 23, 27, 28 and 30-33 are pending and are on appeal.

(4) STATUS OF AMENDMENTS

The claims were last amended in the amendment mailed on July 17, 2003. An amendment after final rejection was mailed on December 20, 2002. In the Advisory Action mailed January 15, 2003, the Examiner indicated that this amendment would not be entered. An appendix sets forth the claims on appeal.

(5) SUMMARY OF THE INVENTION

The claims are directed to a system for monitoring and responding to the environment of an implanted device (claims 1-32) and the implantable device which may be implemented in this system (claim 33). The system includes one or more sensors configured for monitoring data related to variables such as electrical, magnetic, mechanical, fluid flow, chemical, and thermal properties in the device or its surroundings (page 6, line 30 – page 7, line 10), and at least one actuator configured for implementing a response to the monitored data in the device by causing a configurational change in the device (page 14, lines 5-10; page 17, lines 3-5). In one embodiment, the system also includes a means for storage of data, which may be configured to the device or contiguous to the device (page 10, line 30 – page 11, line 3) or within or on the

body of the patient (page 4, lines 15-17). In another embodiment the system includes a means for telemetry (page 3, lines 14-19), such as an analog or digital electronic device (page 4, lines 17-21). In a further embodiment, the system also includes a means for communication to one of a series of nested loops of information exchange (page 14, lines 13-19). An external input can be connected through the loops to effect a change in the device from at least one actuator (page 16, lines 5-11). In yet another embodiment, the system may include a monitoring device configured for positioning external to the patient (page 11, lines 4-8).

The sensor can be configured to detect changes in pH, temperature, ion concentration, or analyte concentration (page 6, line 30 – page 7, line 4). A means for receiving and transmitting signals from one or more of the sensors may be incorporated into the system (page 11, lines 5-8). The system may also provide a means for remotely accessing the data monitored by the sensors (page 11, line 28 – page 12, line 8). In one embodiment, at least one sensor is connected to a means for transmitting or receiving data from a computer or phone communication means (page 17, lines 15-20). The sensors may be configured to monitor the fouling of the device over time, by measuring properties such as protein deposition or formation of a bacterial film on a biliary stent, increase in calcification of a urinary stent, and neointimal thickening of an arterial stent (page 7, lines 15-19).

The system can also include one or more sensors for monitoring the general environment of the implanted device (page 13, lines 13-15), monitoring means (page 11, lines 4-8), and one or more sensors configured for communicating information to the monitoring means and to each other, and configured for communicating commands to the actuator (page 13, line 12 - page 14,

line 12). In one embodiment, the sensors communicate information to a computer transmitting the information to another computer via the internet, for example, via a posting to the internet (page 17, linrd 23-27; Figure 4b).

The claims are further directed to an implantable device which includes one or more sensors configured for monitoring at least one condition (page 13, lines 13-15) and at least one actuator configured for implementing a response to the monitored condition in the device by causing a configurational change in the device (page 14, lines 5-10; page 17, lines 3-5), in which one or more sensors and at least one actuator are configured for control by at least one apparatus external to the implantable device (page 17, lines 15-22; page 13, line 30 – page 14, line 2).

(6) ISSUES ON APPEAL

(1) whether claims 1-9, 19, 22 and 33 were properly rejected under 35 U.S.C. § 102(b) as lacking novelty over U.S. Patent No. 4,146,029 to Ellinwood, Jr.;

(2) whether claims 1-9, 19, 22, 23 and 30-33 were properly rejected under 35 U.S.C. § 102(e) as lacking novelty over U.S. Patent No. 6,248,080 to Miesel, et al.; and

(3) whether claims 27-28 were properly rejected under 35 U.S.C. § 103(a) as obvious over Ellinwood, Jr. in view of U.S. Patent No. 5,411,551 to Winston, et al.

(7) GROUPING OF CLAIMS

The claims do not stand or fall together as discussed below.

(8) ARGUMENTS

(a) The Claimed Invention

Medical implants have been widely used in fields of medicine and surgery such as gastroenterology, urology, and cardiology. Typically, these conventional devices are static and non-interactive. Recently, modifications have been made to include a sensor, making the implant more than a simple structural or augmentative device. These remotely interactive implants include, for example, non-invasively recharged pacemakers, as well as other implants equipped with sensors which can transmit data to a remote reader. However, none of these devices are responsive to the data which is collected by the sensors, nor do they incorporate a means for repeated or interval or programmed interrogation, either intrinsically or extrinsically. None of these devices are able to process and interpret the signal within the device, store the raw or processed data, or telemeter and interact with data transmission or communication means which exist as single or multiple loops of information transfer. Furthermore, none of these devices has incorporated intrinsic or proximate means for alteration of the local environment as a result of gathered information. Appellant's invention allows not only for monitoring and collection of data from the environment surrounding an implant, but also for a means to process, store, and intrinsically respond to the collected data, as well as remote interaction with and control of the implanted device via various communication means.

The claimed system and implantable device to be incorporated into the system allow for the monitoring of the local environment surrounding the implant via sensors, and the modification of the implant or mounting of a response in response to measurements made using the sensors or external dependent or independent signals. The feedback from the sensors, either directly or indirectly via monitoring means external to the patient, signal the required changes.

The sensor can be programmed to transmit continuously or on a regular schedule, and transmit more frequently upon the sensing of a certain condition.

In one embodiment, a person such as a physician or the patient, can monitor the transmissions from the sensor by means of a portable device. The sensor can also be configured to transmit to a receiving unit which would post the data to a web page which is accessible to the patient and physician. The webpage can further be equipped with password protection so that the data is accessible only by the physician and patient. Furthermore, another separate password allows only the physician to access the data and issue commands to the device based on the data collected by the sensors. This system allows the physician to interrogate and issue commands for modifications to the implant non-invasively and remotely. Furthermore, the implant is equipped with an actuator capable of receiving signals and implementing the necessary changes, thus reducing the need to meet directly with the physician.

In another embodiment, the implant may be programmed to have the actuator carry out certain actions in response to the sensing of certain conditions. For example, the physician may program the implant with a certain schedule of therapeutic activity. Alternatively, the physician might program the implant to maintain one schedule under a certain condition and another schedule (either more or less frequent) when the sensors sense a different condition. This feedback system allows for the direct and immediate treatment of a developing condition without external commands from the physician.

(b) Rejections Under 35 U.S.C. § 102

(i) The legal standard

Anticipation requires the disclosure, in a single prior art reference, of every element of the claim. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 231 USPQ 81, 90 (Fed. Cir. 1986). Absence of a claimed element from a prior art reference negates anticipation. Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984).

Scripps Clinic & Research Found v Genentech Inc, 18 USPQ2d 1001 (Fed. Cir. 1991). The Federal Circuit held in *Scripps*, 18 USPQ2d at 1010:

> Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . *There must be no difference* between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. (Emphasis added)

A reference that fails to disclose even one limitation will not be found to anticipate, even if the missing limitation could be discoverable through further experimentation. As the Federal Circuit held in *Scripps, Id.*:

> [A] finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations. The role of extrinsic evidence is to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill in the gaps in the reference.

For a prior art reference to anticipate a claim, it must enable a person skilled in the art to practice the invention. The Federal Circuit held that "a §102(b) reference must sufficiently describe the claimed invention to have placed the public in possession of it. . . [E]ven if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling." *Paperless Accounting Inc v Bay Area Rapid Transit Sys.*, 231 USPQ 649, 653 (Fed. Cir. 1986) (citations omitted).

(ii) Rejection of Claims 1-9, 19, 22 and 23 under 35 U.S.C. § 102(b) over U.S. Patent No. 4,146,029 to Ellinwood, Jr.

Ellinwood, Jr.

Ellinwood discloses a drug delivery device which is responsive to external operator control (col. 3, lines 9-16). There is no specific support for a means of sensing. Col. 7, lines 1-52, refers to sensors, but does not state that they are part of the device. To the extent this sensor could be construed to be part of a "system", it is distinguished in claims 1 and dependent claims and claim 33 by virtue of the inclusion of an actuator in appellant's system, which causes a configurational change in the device as a result of input from the sensors. Ellinwood does not disclose a system whereby data goes from sensors through an actuator to cause a change in the device. Therefore Ellinwood does not anticipate the claims.

(iii) Rejection of Claims 1-9, 19, 22, 23 and 30-33 under 35 U.S.C. § 102(e) over U.S. Patent No. 6,248,080 to Miesel, et al.

Miesel, et al.

Miesel discloses an implantable medical device for measuring intercranial pressure or temperature, which is detected externally, in some cases using telemetric means. There is no direct interaction from sensors and the device via an actuator. The device is not even responsive to signals generated as a result of communication between the sensors and external manipulation, but is merely a data gathering device for external monitoring. To the extent the device includes any responsive element, it is for drug delivery (col. 6, lines 27-42). Therefore Miesel et al does not anticipate the claimed subject matter.

(iv) The Dependent Claims

There are several features defined by the dependent claims which are clearly not in the prior art, which the examiner appears to have overlooked.

For example, claim 2 requires a data storage means. Claim 3 requires that the data storage means is configured to be placed on or contiguous with the device or within the body of the patient.

Claim 6 requires the system include means for communication to one of a series of nested loops or information exchange. Claim 7 requires an external input connected through loops to effectuate change from at least one of the actuators. Claim 30 requires sensors for monitoring the environment of the implanted device, monitoring means, and means for the sensors to

communicate with the monitoring means and each other, and for communicating commands to the actuator.

Claim 23 requires at least one sensor to be connected to means for transmitting or receiving data from a computer or phone communication. Claims 31 and 32 require that the sensors communicate with a computer via the internet.

None of these features are present in either cited reference.

(c) Rejections Under 35 U.S.C. § 103

(i) The legal standard

The U.S. Patent and Trademark Office has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Warner et al.*, 379 F.2d 1011, 154 U.S.P.Q. 173, 177 (C.C.P.A. 1967), *In re Fine,* 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598-99 (Fed. Cir. 1988). In rejecting a claim under 35 U.S.C. § 103, the Examiner must establish a *prima facie* case that: (i) the prior art suggests the claimed invention; and (ii) the prior art indicates that the invention would have a reasonable likelihood of success. *In re Dow Chemical Company,* 837 F.2d 469, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988).

The prior art must provide one of ordinary skill in the art with the motivation to make the proposed modifications needed to arrive at the claimed invention. *In re Geiger*, 815 F.2d 686, 2 U.S.P.Q.2d 1276 (Fed. Cir. 1987); *In re Lalu and Foulletier*, 747 F.2d 703, 705, 223 U.S.P.Q. 1257, 1258 (Fed. Cir. 1984). Claims for an invention are not *prima facie* obvious if the primary references do not suggest all elements of the claimed invention and the prior art does not suggest the modifications that would bring the primary references into conformity with the application

claims. *In re Fritch*, 23 U.S.P.Q.2d, 1780 (Fed. Cir. 1992). *In re Laskowski*, 871 F.2d 115 (Fed. Cir. 1989). This is not possible when the claimed invention achieves more than what any or all of the prior art references allegedly suggest, expressly or by reasonable implication. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680 16 USPQ2d 1430 (Fed. Cir. 1990)

Further, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

(ii) Rejection of Claims 27-28 under 35 U.S.C. § 103(a) over Ellinwood, Jr. in view of U.S. Patent No. 5,411,551 to Winston, et al.

Winston, et al.

Winston discloses only a stent that includes a sensor for glucose. The sensor is located on the inside of the expandable stent wall, which is directly connected to a remote monitoring device.

The Combination of Ellinwood and Winston

Ellinwood, as note above, only discloses devices for drug delivery. Winston discloses a stent with a glucose sensor. There is no teaching of how one could make a device responsive to

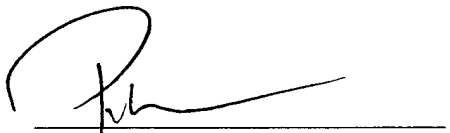
data derived from the stent. There is no disclosure of an actuator. While it may be known that fouling affects the measurements of a sensor, and therefore measurement of the discrepancy of the sensor readings would be representative of fouling, the art fails to teach a means of monitoring fouling.

Claims 27-28 are directed to a sensor with capabilities of measuring properties of fouling (ie, protein deposition or formation of bacterial film) by measurement of changes in mass, wall thickness, or wall shear. Neither Ellinwood nor Winston disclose sensors capable of monitoring these properties. Accordingly, Ellinwood in combination with Winston cannot make obvious the subject matter of the claims.

(9) SUMMARY AND CONCLUSION

For the foregoing reasons, Appellant submits that the claims 1-9, 19, 22, 23, 27, 28 and 30-33 are patentable.

Respectfully submitted,



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Date: March 21, 2003

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Aisha Wyatt

Date: March 21, 2003

Appendix: Claims On Appeal

1. (amended) A system for monitoring and responding to the environment of an implanted device comprising:

one or more sensors configured for monitoring data relating to variables selected from the group consisting of electrical, magnetic, mechanical, fluid flow, chemical, and thermal properties in the device or its environment in a patient, and

at least one actuator configured for implementing a response to the monitored data in the device by causing a configurational change in the device.

2. The system of claim 1 which includes a data storage means.

3. (amended) The system of claim 2 wherein the data storage means is configured to be placeable on the device or contiguous to the device or within or on the body of the patient.

4. The system of claim 1 which includes a telemetry means.

5. The system of claim 4 wherein the telemetry means is an analog or digital electronic device.

6. The system of claim 1 comprising means for communication to one of a series of nested loops of information exchange.

7. (amended) The system of claim 1 comprising an external input connected through loops to effectuate change in the device from the at least one actuator.

8. (amended) The system of claim 1 additionally comprising monitoring means configured for positioning external to the patient.

9. (amended) The system of claim 1 wherein the sensor is configured to detect changes in pH, temperature, ion concentration, or analyte concentration.

19. (amended) The system of claim 1 comprising transmitting and receiving means to the one or more sensors.

22. (amended) The system of claim 1 further comprising means for remotely accessing the data.

23. (amended) The system of claim 1 wherein at least one sensor is connected to means for transmitting or receiving data from a computer or phone communication means.

27. (amended) The system of claim 1 wherein at least one sensor is configured to measure fouling of the device or at least one sensor over time.

28. (amended) The system of claim 1 wherein at least one sensor is configured to measure protein deposition or formation of a bacterial film on a biliary stent, increase in calcification of a urinary stent, and neointimal thickening of an arterial stent, resulting in an increase in thickness, mass and wall shear.

30. (amended) The system of claim 1 comprising:

(a) one or more sensors for monitoring the general environment of the implanted device;

(b) monitoring means; and

(c) the one or more sensors configured for communicating information to the monitoring means and to each other, and configured for communicating commands to the actuator.

31. (amended) The system of claim 30 wherein the one or more sensors communicate information to a computer transmitting the information to another computer via the internet.

32. The system of claim 31 wherein the transmission over the Internet to another computer is via a posting to the world wide web.

33. (amended) An implantable device comprising:

one or more sensors configured for monitoring at least one condition;

at least one actuator configured for implementing a response to the monitored condition in the device by causing a configurational change in the device; and

the one or more sensors and the at least one actuator configured for control by at least one apparatus external to the implantable device.

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